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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,930	07/21/2003	Vicki Bowman Vance	9536-3	6465

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,930

Applicant(s)

VANCE ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for modulating the expression of a first target sequence in a plant cell, said method comprising transforming said plant cell with an RNA precursor construct, said construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of said first target sequence, classified in class 435, subclass 468, for example.
- II. Claims 6-8, drawn to a method for modulating the expression of a first target sequence in a plant cell, said method comprising transforming said plant cell with an RNA precursor construct, said construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of said first target sequence, wherein said plant cell further comprises a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, classified in class 435, subclass 468, for example.

- III. Claims 9-15, drawn to a method for modulating the expression of a first target sequence in a plant cell, said method comprising transforming said plant cell with an RNA precursor construct, said construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of said first target sequence, wherein said plant cell further comprises a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, wherein said plant cell further comprises an amplicon, said amplicon comprising a targeting sequence that corresponds to a second target sequence, classified in class 435, subclass 468, for example.
- IV. Claim 16, drawn to a method for modulating the expression of a first target sequence in a plant cell, said method comprising transforming said plant cell with an RNA precursor construct, said construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of said first target sequence, wherein said plant cell further comprises a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, wherein said plant cell further comprises an amplicon, said

amplicon comprising a targeting sequence that corresponds to a second target sequence, wherein said amplicon further comprises a DNA sequence corresponding to at least a portion of a viral genome, classified in class 435, subclass 468, for example.

- V. Claims 17-19, drawn to a method for modulating the expression of a first target sequence in a plant cell, said method comprising transforming said plant cell with an RNA precursor construct, said construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of said first target sequence, wherein said plant cell further comprises a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, wherein said plant cell further comprises an amplicon, said amplicon comprising a targeting sequence that corresponds to a second target sequence, wherein said amplicon further comprises a DNA sequence corresponding to at least a portion of a viral genome, wherein said amplicon further comprises a third promoter that drives expression in a plant cell operably linked to the targeting sequence, classified in class 435, subclass 468, for example.
- VI. Claims 20, 23 and 26, drawn to a plant or plant cell stably transformed with an RNA precursor construct, said RNA precursor construct comprising a first

promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of a first target sequence, classified in class 800, subclass 298, for example.

VII. Claims 21 and 24, drawn to a plant or plant cell stably transformed with an RNA precursor construct, said RNA precursor construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of a first target sequence, further comprising a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, classified in class 435, subclass 419, for example.

VIII. Claims 22 and 25, drawn to a plant or plant cell stably transformed with an RNA precursor construct, said RNA precursor construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a precursor RNA, said precursor having at least one miRNA sequence incorporated into the precursor RNA sequence, wherein said miRNA sequence is complementary to a portion of a first target sequence, further comprising a DNA construct comprising a second promoter that drives expression in a plant cell operably linked to a second nucleotide sequence encoding a modulator, further

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comprising an amplicon, said amplicon comprising a targeting sequence that corresponds to a second target sequence, classified in class 800, subclass 298, for example.

For invention I above, restriction to a single first target sequence is also required under 35 USC 121. Therefore, if invention I is elected, a single first target sequence must also be elected.

For invention II above, restriction to a single modulator is also required under 35 USC 121. Therefore, if invention II is elected, a single modulator must also be elected.

For invention III above, restriction to a single second target sequence is also required under 35 USC 121. Therefore, if invention III is elected, a single second target sequence must also be elected.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions III-V and VII-VIII are distinct inventions. The method of invention I requires the use of an RNA precursor construct that differs in structure and function from the RNA precursor constructs used to practice the methods of inventions IV-V and VII-VIII. The method of invention I does not require the use of or result in the production of the plant cell and plants of inventions VII and VIII.

Inventions VI and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the stably transformed plant cell can be made by another and materially different process, such as by isolating a transgenic cell from a transgenic plant.

Invention II and inventions III-VI and VIII are distinct inventions. The method of invention II requires the use of an RNA precursor construct that differs in structure and function from the RNA precursor constructs used to practice the methods of inventions IV-VI and VIII. The method of invention II does not require the use of or result in the production of the plant cell and plants of inventions VI and VIII.

Inventions VII and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the stably transformed plant cell can be made by another and materially different process, such as by isolating a transgenic cell from a transgenic plant.

Invention III and inventions IV-VII are distinct inventions. The method of invention III requires the use of an RNA precursor construct that differs in structure and function from the RNA precursor constructs used to practice the methods of inventions IV and V. The method of invention III does not require the use of or result in the production of the plant cell and plants of inventions VI-VII.

Inventions VIII and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the stably transformed plant cell can be made by another and materially different process, such as by isolating a transgenic cell from a transgenic plant.

Invention IV and inventions V-VIII are distinct inventions. The method of invention IV requires the use of an RNA precursor construct that differs in structure and function from the RNA precursor construct used to practice the method of invention V. The method of invention IV does not require the use of or result in the production of the plant cell and plants of inventions VI-VIII.

Invention V and inventions VI-VIII are distinct inventions. The method of invention V does not require the use of or result in the production of the plant cell and plants of inventions VI-VIII.

Invention VI and inventions VII-VIII are distinct inventions. The plant cell and plant of invention VI comprise an RNA precursor construct that differs in structure and function from the RNA precursor constructs comprised by the plant cells and plants of inventions VII and VIII.

Invention VII and invention VIII are distinct inventions. The plant cell and plant of invention VII comprise an RNA precursor construct that differs in structure and function from the RNA precursor construct comprised by the plant cell and plant of invention VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their recognized divergent

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subject matter, and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


1/26/06